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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/725,010	11/29/2000	Paula Sundstrom	23878.0005	8550

23767 7590 04/07/2004

PRESTON GATES ELLIS & ROUVELAS MEEDS LLP  
1735 NEW YORK AVENUE, NW, SUITE 500  
WASHINGTON, DC 20006

EXAMINER

ZARA, JANE J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8M.

**Office Action Summary****Application No.**

09/725,010

**Applicant(s)**

SUNDSTROM, PAULA

**Examiner**

Jane Zara

**Art Unit**

1635

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-7,11,19-21 and 27-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-7,11,19-21,27-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The finality of the Office action mailed 1-5-04 is hereby vacated in light of the non-final rejection set forth below.

This Office action is in response to the communication filed 10-2-03.

Claims 1, 4-7, 11, 19-21, 27-32 are pending in the instant application.

### ***Response to Arguments and Amendments***

#### **Withdrawn Rejections**

Any rejections not repeated in this Office action are hereby withdrawn.

#### **Maintained Rejections**

Claims 1, 4-7, 11, 19-21, 27-32 are rejected under 35 U.S.C. 112, first paragraph, for lacking adequate written description for the reasons of record set forth in the Office action mailed 7-2-03 and as discussed below.

The claimed invention encompasses the ability to interfere with any hyphal-specific gene in *C. albicans*, via any cis-acting sequence that mediates the transcription of any hyphal-specific gene, wherein growth of *C. albicans* is inhibited.

Applicant's arguments filed 10-2-03 have been fully considered but they are not persuasive. Applicants argue that adequate description has been provided for the claimed invention, and that the written description rejection is inappropriately rationalized because it relies on the Lilly rationale. Contrary to applicants' assertions, the instant written description rejection is not limited to the situation posed in Lilly, and is appropriate for the instantly claimed invention. The invention is drawn to a method of interfering with transcription of hyphal

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specific genes in *C. albicans* mediated by cis acting sequences. The examples provided in the instant disclosure, including the various hyphal specific genes SAP6, ALS3, HYR, ECE1, are not adequately representative of all hyphal specific genes in *C. albicans*. Furthermore, the examples provided for cis acting sequences including UAS and UAR are not adequately representative of all cis acting sequences participating in the transcriptional regulation of all hyphal specific genes in *C. albicans*. The prophetic disclosure of DNA binding proteins that have been reported in the literature and that may bind and mediate other possible cis acting sequences does not substitute for adequate written description or enablement of the broadly claimed invention drawn to any cis acting sequences mediating the transcription of any hyphal specific genes in *C. albicans*.

Applicant argues that one skilled in the art would be able to, by routine experimentation, adequately identify and describe the deletions, mutations, insertions and modifications of the hyphal specific sequence of SEQ ID NO: 1. Contrary to applicant's assertions, no deletions, mutations, insertions and modifications of the hyphal specific sequence of SEQ ID NO: 1 have been described in the instant disclosure. The specification does not describe the criteria, characteristics and guidance for the identifying characteristics of such mutations, deletions, insertions or modifications of the hyphal specific sequence of SEQ ID NO: 1. Thus Applicant was not in possession of the claimed invention. Therefore, the written description rejection is maintained.

Claims 1, 4-7, 11, 19-21, 27-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for correlating expression patterns of HWP1 mRNA with development of *C. albicans*, for detecting an increase in HWP1 mRNA in *C. albicans* when grown under inducing, compared to repressive, conditions, for obtaining a nested deletion

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comprising approximately 83 nucleobases upstream of the TAT box of the HWP1 promoter, and for correlating a failure of mice to thrive with orally colonized *C. albicans*, compared to mice infected with a null mutant strain (HWP<sup>-</sup> *C. albicans*), does not reasonably provide enablement for the ability to interfere with the expression of any hyphal specific genes in *C. albicans* by interfering with transcription of hyphal specific genes mediated by any cis acting sequences, for the reasons of record set forth in the Office action mailed 7-2-03.

Applicants argue that the instant invention is adequately described and enabled for its full scope and that existing methodologies have been cited for identifying the cis acting sequences present within the gene product claimed and for identifying the DNA binding proteins that may interact with the cis acting sequences within the gene product. Contrary to applicant's assertions, it would take undue experimentation to utilize existing methodologies to identify all, or a representative number of species of the broad genus comprising all cis acting sequences that mediate the transcription of any hyphal specific genes in *C. albicans*, whereby *C. albicans* growth is inhibited.

Applicants argue that all of the Wands factors have been adequately addressed and that the quantity of experimentation required to enable the full scope of the invention is not undue, and furthermore that the specification does not have to exemplify every aspect of the claim in order to enable the full scope. Contrary to applicant's assertions, the quantity of experimentation required to enable the scope claimed includes the teaching of methods of interfering with the expression of a representative number of hyphal specific genes by interfering with the transcription of a representative number of hyphal specific genes mediated by a representative number of cis acting sequences. The specification fails to provide adequate teachings for the

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interference of transcription of any hyphal specific gene by any cis acting sequences. It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See *Ex parte Singh*, 17 USPQ2d 1714 (BPAI 1991). Therefore, the enablement rejection is maintained.

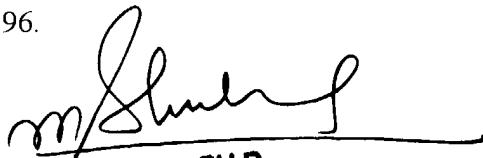
### ***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is **703-872-9306**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (571) 272-0760. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ

4-1-04



**RAM R. SHUKLA, PH.D.**  
**PRIMARY EXAMINER**